UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte YADONG HUANG,
ROBERT W. MAHLEY and JOHN M. TAYLOR

Appeal No. 2004-1720
Application No. 09/544,910

ON BRIEF

Before SCHEINER, ADAMS, and GREEN, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

REMAND TO THE EXAMINER

This case is remanded to the examiner to clarify the status of the rejection under 35 U.S.C. § 102(b) over Kasiske as evidenced by Wyne. In the final rejection, the rejection was applied to claims 1, 5, 6 and 11. See Paper No. 21. In addition, appellants' Brief also states that the rejection applies to claims 1, 5, 6 and 11. See Appeal Brief, pages 8 and 32. The Examiner's Answer, however, states that the rejection applies to claims 1, 4-8 and 11, all of the pending claims. The Examiner's Answer acknowledges that the rejection is set forth in the Final Rejection, Paper No. 21, but does not acknowledge that the rejection has been

applied to claims that were not rejected in the Examiner's Answer. See Examiner's Answer, page 10. Finally, in the Reply Brief, appellants again state that the rejection applies to claims 1, 5, 6 and 11, and do not make mention of the fact that the Examiner's Answer applied the rejection to claims 1, 4-8 and 11. See Reply Brief, page 13.

The panel would also like to take this opportunity to comment on the rejection under 35 U.S.C. § 112, first paragraph, as containing subject matter that is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention, i.e., lack of adequate written description.

According to the rejection,

> The written description sets forth a catalog of various generic types of agents that may possibly meet the requirements of the claims. For example, the specification teaches that the agent may be an "apoE inhibitor" (page 10, line 2). Furthermore, the specification teaches that "the apoE inhibitor may be a number of different types of agents, such as small molecules, antibodies or binding fragments thereof, and the like" (page 10, lines 5-6). The specification also teaches that "agents are also found among biomolecules, including peptides, saccharides, fatty acids, steroids, purines, pyrimidines, derivatives, structural analogs or combinations thereof" (page 10, lines 15-17). Then, on page 14, the specification teaches that antisense nucleic acid molecules are contemplated for use as agents in practicing the claimed invention (line 11). Finally, on page 18, lines 8-9, the specification teaches that catalytic nucleic acids [sic] molecules, such as ribozymes, could be used as agents.
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> However, the specification does not distinctly and specifically point out the identity of even one agent suitable for use in practicing the invention as claimed. The disclosure of a catalog of potentially effective agents is deemed an insufficient written description of the agent of the claims because it would not reasonably convey to the

skilled artisan that Appellants had possession of the claimed invention at the time the application as filed.

Examiner's Answer, pages 7-8.

Claim 1, which is representative of the claims on appeal, reads as follows (emphasis added).

1. A method for reducing the plasma level of VLDL in a host, said method comprising:
administering to said host an effective amount of an agent which reduces the amount of plasma active apoE in said host by reducing the expression of apoE by an amount sufficient to reduce VLDL production in said host to reduce the plasma level of VLDL in said host, whereby the plasma level of VLDL in said in said host is reduced by at least two fold.

There appears to be some dispute how to construe the claim limitation "reducing the expression of apoE." The examiner construes the limitation as not being limited to any particular mechanism. The examiner asserts that "any agent, which when administered to a host, causes a reduction in the amount of apoE that is 'expressed', or which is present at the time of the sampling in the host to whom the agent is administered would appear to fulfill the requirements of the claims, absent a showing of any difference." Appeal Brief, paged 21-22.

Appellants, on the other hand, define "reducing the expression of apoE" as "reducing transcription of the gene encoding apoE and/or translation of an mRNA encoding apoE." Appeal Brief, page 25. That construction, however, conflicts with the arguments appellants made in response to the written description rejection. Appellants argue that "the specification provides a description of at least three types of agents that can be used in the claimed methods." Appeal Brief, page 13 (emphasis in original). Specifically, appellants argue that "[t]he

specification states that small molecules are useful for reducing plasma active apoE. Specification, page 10, lines 1-17. The specification states that the agent may be an apoE inhibitor. Specification, page 10, lines 2-6." Appeal Brief, page 13. As defined on page 10 of the specification, an apoE inhibitor "interacts with plasma active apoE is [sic] such a manner as to render the apoE inactive." Specification, page 10. If such apoE inhibitors are a description of the claimed inhibitors, then the examiner's interpretation would be more correct.
Upon remand, therefore, we suggest that both appellants and the examiner revisit the construction of the phrase "reducing transcription of the gene encoding apoE and/or translation of an mRNA encoding apoE."

In addition, while the panel is not addressing the merits of the appeal, the examiner may wish to revisit the written description rejection. As noted by appellants, the nucleotide sequence of the mRNA encoding apoE was known at the time of filing. See Appeal Brief, page 13. Thus, the examiner should focus on why that would not constitute adequate written description when coupled with the specification's disclosure that antisense technology and ribozymes may be used to reduce the expression of apoE.

FUTURE PROCEEDINGS

We state that we are not authorizing a Supplemental Examiner's Answer. This application, by virtue of its "special" status, requires an immediate action. MPEP § 708.01 (7th ed., rev. 1, February 2000). It is important that the Board be informed promptly of any action affecting the appeal in this case.

REMANDED

TONI R. SCHEINER
Administrative Patent Judge

DONALD E. ADAMS
Administrative Patent Judge

LORA M. GREEN
Administrative Patent Judge

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